

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**WILLIAMSON ET AL**

Atty. Ref.: **620-373**

Serial No. **10/536,804**

Group: **1642**

Filed: **November 10, 2005**

Examiner: **Reddig, Peter J.**

For: **CANCER ASSOCIATED PLEXIN B1 MUTATIONS**

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Mail Stop PETITIONS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION PURSUANT TO MPEP §608.01(p)I.A.2.<sup>1</sup>**

1. I, B. J. Sadoff, am a registered attorney representing the applicants in the above at the request and direction of the assignee. I am an attorney associated with Customer No. 23117 as listed in the PTO IFW of the above.

2. An Amendment filed December 24, 2008 revised the Specification to include a Sequence Listing which included an amino acid and nucleic acid sequence of sequence accession number AB007867 of the originally-filed specification. A copy of the AB007867 sequence was supplied by the Examiner as an attachment to the Office Action dated March 6, 2009.

3. The sequence accession number AB007867 of the originally-filed specification (see at least pages 8 and 12 of the originally-filed specification) has been included in

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<sup>1</sup> [http://www.uspto.gov/web/offices/pac/mpep/documents/0600\\_608\\_01\\_p.htm#sect608.01p](http://www.uspto.gov/web/offices/pac/mpep/documents/0600_608_01_p.htm#sect608.01p)  
(December 11, 2009).

WILLIAMSON ET AL

Serial No. 10/536,804

DECLARATION PURSUANT TO MPEP §608.01(p)I.A.2.

December 21, 2009

the specification with the Amendment filed December 24, 2008. The material which has been inserted with the Amendment filed December 24, 2008 is the material previously incorporated by reference. The Amendment filed December 24, 2008 contains no new matter.

4. For completeness, it is noted that the effective date of Rule 57 is October 21, 2004 (see 69 FR 56481 dated September 21, 2004). As the present application is a U.S. national phase of a PCT application filed November 28, 2003, the following description of incorporation-by-reference, as found in MPEP § 608.01(p) (Rev. 2, May 2004) (see [www.uspto.gov](http://www.uspto.gov)) applies to the present application:

#### I. INCORPORATION BY REFERENCE

The \*>Director< has considerable discretion in determining what may or may not be incorporated by reference in a patent application. General Electric Co. v. Brenner, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). The incorporation by reference practice with respect to applications which issue as U.S. patents provides the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The following is the manner in which the \*>Director< has elected to exercise that discretion. Section A provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section B provides guidance for incorporation by reference in benefit applications; i.e., those domestic (35 U.S.C. 120) or foreign (35 U.S.C. 119(a)) applications relied on to establish an earlier effective filing date. >See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.<

A. Review of Applications Which Are To Issue as Patents.

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. Ape. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below.

"Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.

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## 2. Improper Incorporation

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the reference. In such a case, the applicant will be required to amend the specification to include the material incorporated by reference.

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The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

WILLIAMSON ET AL  
Serial No. 10/536,804  
DECLARATION PURSUANT TO MPEP §608.01(p)I.A.2.  
December 21, 2009

5. The present Declaration is submitted in accordance with the above-quoted requirements of MPEP § 608.01(p) (May 2004). The December 24, 2008 amendments to the specification consist of the same material incorporated by reference in the referencing application.

6. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By /B. J. Sadoff/  
B. J. Sadoff  
Registration No. 36663

Date: December 21, 2009